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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,251	04/10/2000	NAOSHI FUKUSHIMA	065678/0101	9585

7590 07/11/2002

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EXAMINER
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HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/11/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/508,251

Applicant(s)

FUKUSHIMA ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/7/02 and interview summary mailed 7/8/.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 22-23 have been canceled.  
Claims 13, 18, and 20 have been amended.  
Claims 13-21 are under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejection.

***Rejections Withdrawn***

4. The rejection of claims 20-21 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.
7. The rejection of claim 19 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the evidence of deposit.
8. The rejection of claims 13-14, 20-21 under 35 U.S.C. 102(b) as being anticipated by Mawby et al (Biochem J. 304:525-530, 1994, IDS #5) is withdrawn in view of the amendments to the claims and arguments.

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9. The rejection of claims 13-14 under 35 U.S.C. 102(b) as being anticipated by Lindberg et al (The Journal of Cell Biology 123:485-496, 1993, IDS #5) as evidenced by Petterson (Apoptosis 5:299-306, 2000) is withdrawn in view of the amendments to the claims.

11. The rejection of claims 13-14 and 17 under 35 U.S.C. 103(a) as being unpatentable over Lindberg et al (The Journal of Cell Biology 123:485-496, 1993) and as evidenced by Petterson (Apoptosis 5:299-306, 2000) as applied to claims 13-14 and 20-22 above, and further in view of Goding (Monoclonal Antibodies: Principles and Practice, Second Ed, pages 125-129, 1986) is withdrawn in view of the amendment to the claims.

### ***Response to Arguments***

9. The rejection of claims 20-21 under 35 U.S.C. 102(b) as being anticipated by Lindberg et al (The Journal of Cell Biology 123:485-496, 1993, IDS #5) as evidenced by Petterson (Apoptosis 5:299-306, 2000) is maintained.

The response filed 5/7/02 has been carefully considered but is deemed not to be persuasive. The response states that "not all of the anti-CD47 antibodies are capable of causing the death on nucleated blood cells. Moreover, applicants have amended claim 13 to exclude Petterson's 1F7 antibody" (see page 4 of response). In response to these arguments, claim 20 does not recite this limitation and as stated in the previous Office action the 1F7 antibody causes apoptosis.

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11. The rejection of claims Claims 15-16, 18, 20-21 under 35 U.S.C. 103(a) as being unpatentable over Lindberg et al (The Journal of Cell Biology 123:485-496, 1993) and as evidenced by Petterson (Apoptosis 5:299-306, 2000) as applied to claims 13-14 and 20-21 above, and further in view of Goding (Monoclonal Antibodies: Principles and Practice, Second Ed, pages 125-129, 1986) is maintained.

The response filed 5/7/02 has been carefully considered but is deemed not to be persuasive. The response states "As stated in the earlier sections, both Lindberg et al and Petterson et al, (2000) are not anticipatory to the claimed invention" and "Neither is there any suggestion nor motivation to modify the teachings of Lindberg with Goding's method" (see page 5 of response). In response to these arguments, Again, the claims do not recite the limitation of "other than 1F7" therefore the antibody of Lindberg et al reads on the claims. In addition, there is ample motivation to combine the teachings of Lindberg et al with Goding as stated in the previous Office Action because Goding teach that it may be desirable to generate antigen binding fragments of antibodies in order to remove the Fc region that can bind nonspecifically to cells and the small size of the fragments may aid in penetration into tissues (see page 125-126). In addition, it would have been obvious to produce hybridomas of the antibodies because this is routine in the art.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

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***The following are some NEW GROUNDS of rejections.***

***Claim Rejections - 35 USC § 112***

Claims 13-14, 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 has been amended to recite the limitation of "said monoclonal antibody is other than 1F7". In the response file 5/7/02 it is stated that support for the amendment can be found throughout the entire specification, specifically at page 4, lines 6-11 and page 5, lines 20-25. Upon review of the recited pages the examiner does not find support for the newly added limitation. The recited locations in the specification disclose nothing about the 1F7 antibody. Applicants are required to provide specific support in the specification as originally filed for the limitation or remove it from the claim. .

***Conclusions***

12. No Claims are allowed. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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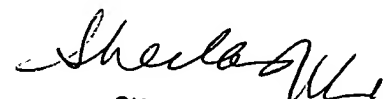
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

  
SHEELA HUFF  
PRIMARY EXAMINER

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